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TITLE: PILOT TRIAL OF POTENTIATING NORMAL HEALING OF STRESS FRACTURES USING PULSING ELECTROMAGNETIC FIELDS

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13. ABSTRACT *(Maximum 200 words)*

Stress fractures usually take a long time to heal and prevent soldiers from participating in most physical activities. About half of the trainees at Ft. Sill diagnosed with stress fractures never return to active duty. This pilot tests the feasibility of using pulsing electromagnetic fields, such as those used to potentiate the healing of non-unions, to speed healing of stress fractures. In the first trial, the field coil was embedded in the cast to produce a magnetic field around the fracture. The unit was supposed to be used for a minimum of six weeks but, due to a change in treatment policies resulting from a turnover in staff with desert shield, the units were only used for a few weeks. Eighteen trainees used the units in their casts, ten just had casts (the standard treatment) during the treatment period and thirty-one just had the standard treatment before the treatment period. There was no difference between number of days it took those members of the groups able to return to duty to do so. However, Only two of the treated soldiers had MEBs while twenty of the controls did. The pilot will continue as an unfunded study at Ft. Sill. The proposed work and new investigators were identified in the annual report to MRDC for this project dated 6 November, 1992.

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Program Director's Signature   Date

Pilot trial of potentiating normal healing of stress fractures using pulsing electromagnetic fields
USAMRDC # 9012402, HSC # 90366, FAMC #90-206

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INTRODUCTION:

1. Aim of pilot: To determine whether pulsing magnetic fields added to standard treatments of soldiers in basic training who are diagnosed as having tibial stress fractures will produce a sufficient reduction in time away from training and in proportion of soldiers lost to the service that a full study will be warranted.

2. Hypothesis for pilot: That pulsing magnetic fields applied to soldiers diagnosed as having tibial stress fractures will produce a sufficient reduction in time away from training and in proportion of soldiers lost to the service that a full study will be warranted.

3. Objective for pilot: To demonstrate that a full study of pulsing magnetic fields is warranted for treatment of stress fractures.

4. Goal for Part One (reported in this final report): To demonstrate that addition of pulsing magnetic fields to standard treatment significantly reduces the time to return to duty and the number of MEBs for stress fractures among basic trainees.

5. Goals for Part Two (work described in the annual report dated 6 November, 1993):

a. Establish a stable team to perform the rest of the pilot with a controlling principal investigator on site at Ft. Sill.

b. Hold the "standard" treatment consistent long enough to perform the pilot so meaningful comparisons between the groups can be made.

c. Follow all subjects through graduation from basic so any reoccurrence of the disorder can be monitored.

d. Demonstrate that addition of pulsing magnetic fields to standard treatment significantly reduces the time to return to duty and the number of MEBs for stress fractures among basic trainees.

6. Significance:

a. To the Army: Any methodology which can even marginally reduce the high rate of temporary disability occurring during initial training would significantly increase the efficiency of the training effort. This study has the potential to demonstrate a technique which could significantly reduce the amount of time lost to training and the number of trainees entirely lost to the Army due to stress fractures.

b. To medical science: We are interested in stress fractures because they are true fractures which do not normally have significant movement at the fracture site. Thus, they are excellent test beds for evaluation of techniques to speed healing because they are not complicated by the presence of the usual variety of appliances surrounding a fracture.

7. Status of the literature:

a. Lower extremity injury rate during basic training: the US Army Research Institute of Environmental Medicine recently completed a review and study of both the incidence and risk factors for injury among Army basic trainees [1,2]. These exhaustive reviews of the literature were combined with detailed studies of actual injury rates among basic trainees. The excellent prospective studies concluded that 51% of females and 27% of males are injured during basic training. Of 124 men and 186 women studied in detail, the men lost 99 days of full training while the women lost 481 days of full training. However, initial physical fitness was an excellent predictor of injury and when pre-training level of fitness was factored in, the difference between males and females disappeared. The risk of sustaining lower extremity injuries sufficiently severely to significantly interfere with training was 45% for females and 21% for males. Of these, 11% of females and 2 percent of males sustained stress fractures. In a separate study, 129 sustained injuries to their lower extremities which resulted in significant losses of training time. Nine of these were stress fractures. Illness rates were similar for both sexes (after adjustment for gynecological problems) and only caused a loss of 23 and 19 full training days for women and men respectively. The results of these studies parallel the results of the large demographic and clinical studies reviewed by the authors. These rates of injury become especially noteworthy when it is noted that traumatic events initiating the problems are rare. Volpin et al[3] recently reviewed 105 lower limb pain cases among recruits and found that 54% had stress fractures when diagnosed using technesium scans. Of the remaining recruits without evidence of stress fractures, 74% had anatomical deformities of the lower limb. Thus, stress fractures during basic training are a very significant factor in training effectiveness.

b. Use of pulsing magnetic fields for helping delayed union and nonunion fractures heal: Uncontrolled clinical trials have reported the use of low frequency pulsing electromagnetic fields to speed and promote the healing of delayed union and nonunion fractures in clinical trials since the 1970s[4]. At least 14 of the papers report the technique's use for these problems in the tibia. Taken together, they represent trials with 1,275 patients of whom an average of 81% healed after a significant pause in progress[5]. More recently, double blind studies indicating the technique's effectiveness on a wide of bones have been published. For example, Sharrard[4] performed a double blind study of 45 fractures of the tibial shaft and in which 20 received active coils and 25 received dummy units. Orthopedic examination indicated that nine of the subjects in the active group showed healing relative to 3 in the control group. Objective radiological evaluation indicated union of five fractures and progress toward union in an other five fracture in the active group compared with union in one fracture and progress toward union in one fracture in the control group. Thus, the technique has been shown to be effective in helping nonunion and delayed union fractures of the tibia.

We are only aware of one study in which magnetic fields were used with delayed union stress fractures. Conveniently, the study was done with fractures of the tibia[6]. The authors found that of 8 subjects with confirmed delayed unions, 7 healed with a combination of rest and magnetic fields.

The instruments used to produce and apply the field generally consist of a charger, a combined control and generator unit, and a field coil. The unit is worn on the waist and the coil is either embedded into the cast or taped over the fracture site.

c. Use of pulsed magnetic fields to speed healing of normally healing fractures: We are not aware of any studies showing the techniques' usefulness (or lack there of) for speeding the healing of normally healing fractures. However, we are aware that it has been tried clinically and has a mixed reputation for success. The problem is that fractures heal a very different rates due to many known and probably more unknown and idiopathic factors so a very large group of people of similar ages and physical conditions having similar fractures of similar severities who would all get the same treatment would have to be gathered together in one place at about one time in order to evaluate the technique's effect. An other complicating set of factors involves the interference of fracture treatment methodologies such as plates, screws, and etc. with operation of the fields and the fact that each appliance has to be placed differently depending on the needs of the patient. Differences in movement around the fracture also complicate the situation.

d. Use of Pulsed, non-thermal, high frequency electromagnetic energy in the treatment of ankle sprains and wound healing: Pennington et al[7] found that edema from grade one and two ankle sprains was reduced faster among 25 soldiers than among 25 control soldiers. Goldin et al [8] and many others have shown that wounds heal more quickly when exposed to the above types of energy. It is possible that reducing the edema resulting from the stress fracture and increasing the healing rate of associated tissues may decrease the time trainees are disabled. However, it is possible that reducing the edema may decrease the pain to such an extent that trainees feel ready to return to duty before their stress fractures actually heal, become disabled again quickly, and actually delay their final recovery.

e. Potential use of magnetic fields with Army trainees having stress fractures: All of the problems indicated above in evaluating the usefulness of magnetic fields for speeding fracture healing are avoided by using Army trainees diagnosed as having tibial stress fractures as subjects for a study. They are of similar age and condition, large groups are available in one place and at about one time, all receive the same treatment because they have similar types of fractures of about the same severity, and the fracture sites do not move significantly so are not treated with metal plates, screws, and etc. with alter the magnetic field.

BODY:

1. Methods used in part I: Power analysis of data on trainees at Ft. Sill diagnosed as having tibial stress fractures indicated that at least 30 similar trainees with the same diagnoses should be run at that site (to hold diagnostic and evaluative procedures as well as training factors constant) in order to assess the likelihood that application of magnetic fields would speed return to training and reduce the number of soldiers boarded out of the Army. Each soldier agreeing to participate received the standard casting - no weight bearing, light duty treatment. Eighteen were also instrumented with standard, safe, painless, low frequency pulsing magnetic field generators and coils. Ten soldiers with the same diagnosis were given the above treatment but did not receive the coils so served as concurrent controls. This was done because the methods for evaluating soldiers for return to duty kept changing throughout part I as staff changed over. No change in the normal evaluation and treatment routine was made to minimize the impact of the device's presence on decisions about disposition of the participants and to insure that data from the participants was as similar as possible to that already gathered for the historical controls.

2. Subjects:

(a) Number, source, and sex: The subjects were 28 male soldiers in basic training at Ft. Sill diagnosed as having tibial stress fractures (please note that NO females go through artillery basic at Ft. Sill so we could not include females in our pilot. If it takes place, the full study will include both males and females.)

(b) Inclusion and exclusion criteria: The only entrance criteria were having a tibial stress fracture and willingness to participate in the study while the only exclusion criteria were not being in overall good health other than the stress fracture and having a history of stress fractures.

(c) Subject identification: During participation, subjects were identified by their names and social security numbers because the experimental data had to be related to results of standard medical evaluations and graduation documents. However, all records relating experimental results to subjects' names and numbers were kept locked in a file cabinet. At the end of participation, a code number replaced the names and social security numbers on each record. The key relating the code to the subjects' names and social security numbers is locked in the PI's files. This is necessary in case a follow-up set of evaluations becomes necessary.

(4) Subject assessment: Standard clinical evaluations for resolution of stress fractures and ability to return to duty as performed at Ft. Sill and noted in patients' records. Many types of stress fractures are seen at Ft. Sill. The evaluations of all types of stress fractures are done similarly as are decisions about time to return to duty. There was no way to blind evaluators to the presence of the stimulator but the evaluators were not co-investigators involved in the study so were neutral as far as giving different consideration to the users.

(5) Risk to benefit ratio: maximum benefit to minimum risk. There are no known risks involved in having low frequency magnetic fields over a fracture site.

3. Results of part one: This study has been very difficult to perform to date because virtually the entire staff involved in the project including investigators at Ft. Sill and both the PAs and physicians treating and assessing recruits turned over **twice** during part one! When the study started, the standard treatment for stress fractures was casting for a minimum of six weeks, no weight bearing, and light duty. It gradually changed to two to four weeks of casting with minimal weight bearing and light duty. It is now NO casting, no weight bearing, and light duty.

The field coil was embedded in the cast to produce a magnetic field around the fracture. The unit was supposed to be used for a minimum of six weeks but, due to the change in procedures described above, the units were only used for a few weeks. Eighteen trainees used the units in their casts, ten just had casts (the standard treatment) during the treatment period and thirty-one just had the standard treatment before the treatment period. The details of their participation is summarized in Table I. Among those trainees able to return to regular duty, there was no difference between the groups in the number of days it took them to return (One way Analysis of Variance $F = 1.56$, $p = 0.22$). These data are summarized in table II. Of considerable interest, only two of the treated soldiers had MEBs while twenty of the controls did. Two of the concurrent controls were lost to follow-up and several of those returned to duty were not followed to graduation so whether or not they were actually cured is not known.

CONCLUSION

The results of the study so far are that less of the soldiers who used stimulators had MEBs than those who did not but it takes just as long to return to work. Of course, this may be because more seriously damaged fractures were salvaged. The continuation of this pilot will follow subjects much more closely through their graduations so any reoccurrence of the problem can be noted. It will also use a more stable team with the control centered at Ft. Sill. This should help reduce the number of changes in standard procedures while the pilot is in progress.

Table I: STRESS FRACTURE PILOT STUDY: RESULTS OF FIRST TRIAL

					Time in Days		
Pt #	Fracture Location	Bone Scan	X-ray	Therm onset	Symptom & Dx	Rx'd with PEMF	Rx began & RTD or MEB
SUBJECTS TREATED WITH STANDARD OF CARE PLUS STIMULATION:							
1	L tibia	pos		warm	13	22	MEB 95
2	L tibia	pos		warm	7	20	RTD 28
3	L tibia	pos		warm	46	21	RTD 32
4	B tibia (only left RX'd)	pos		asym.	40	15	RTD 28
5	R tibia	pos		warm	14	21	RTD 22
6	B tibia (only left RX'd)	pos		asym.	12	14	RTD 34
7	L MT #3			WNL	4	18	RTD 32
8	B tibia (only right RX'd)	pos		asym.		20	RTD 29
9	B tibia (pt had numerous other orthopedic complications)	pos		asym.	35	28	EPTS
10	B tibia & L fibula		pos	asym.	48	14	DC'd not med
11	R tibia	pos		warm	51	27	DC'd not med
12	R tibia		pos	warm	29	26	MEB for back
13	B tibia & R fibula (only right Rx'd with PEMF coil)	pos		asym.	47	17	RTD 71
14	L tibia		pos	cool		26	RTD 171
15	L tibia		pos	WNL	26	23	RTD 44
16	B tibia (both RX'd)		pos	asym.	28	10	MEB 115
17	R tibia	pos	pos	warm		2	RTD 30
18	R tibia	pos		cool	46	3	RTD 59
SUBJECTS TREATED WITH STANDARD OF CARE ONLY							
Concurrent Controls:							
19	L#2 MT		pos	cool	27	0	RTD
20	L#3 MT		pos	warm	7	0	RTD
21	L#3 MT	pos		warm	10	0	RTD 30
22	R#1 MT	pos		warm	41	0	unknown
23	R talus	pos		cool	25	0	unknown
24	L#3 MT		pos	varied	12	0	RTD 21
25	B tibia	pos		asym.	18	0	RTD 68
26	R tibia		pos	warm	18	0	RTD 41
27	L tibia & L cuboid bone	pos		asym.	37	0	MEB 60
28	R tibia		pos	warm	28	0	RTD 96
Historical Controls:							
29 - 43	tibia					0	RTD 41 +/- 18
44 - 62	tibia					0	MEB 79 +/- 35

Table II: STATISTICAL RELATIONSHIPS BETWEEN GROUPS IN PART ONE

A. Days between start of treatment and return to regular duty

	GROUPS		
	used stimulator	historical controls	concurrent controls
number of subjects	18	31	10
mean	33.8	41.2	51.2
range	22-59 > 37	19-86 > 67	21-96 > 75
standard deviation	10.5	17.8	30.6
99% confidence limits	25.3 - 42.3	33.0 - 49.4	15.9 - 86.5

ANOVA: F = 1.56, P = 0.2211 > No significant difference between groups!

Independent "T"s between:
used stimulators vs. historical controls:
T = 1.25, one tail p = 1.21
used stimulators vs. concurrent controls:
T = 1.71, one tail p = 0.08

B. Rate of return to duty vs. MEBs

Only data for those with known outcomes at the end of basic training were used. Thus, the concurrent control looks much better than it actually was.

group	return to duty	MEB
used stimulator	12	2
concurrent control	7	1
historical control	15	19

Overall chi square = 10.00, p = 0.007

used stim vs. concurr chi sq = 0.014, p = 0.91

used stim vs. historic control chi sq = 6.97 p = 0.008

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